

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE

**IN RE: VALSARTAN, LOSARTAN,  
AND IRBESARTAN PRODUCTS  
LIABILITY LITIGATION**

**This Document Relates to All Actions**

MDL No. 2875

Honorable Renée Marie Bumb,  
Chief District Court Judge

**Motion Day: October 21, 2024**

**TORRENT'S REPLY MEMORANDUM OF LAW IN SUPPORT OF ITS  
MOTION TO CLARIFY WHETHER DR. NAGAICH MAY TESTIFY AS  
TO CERTAIN TOPICS WITH RESPECT TO WHICH PLAINTIFFS'  
EXPERT, MR. RUSS, HAS BEEN PERMITTED TO TESTIFY**

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Plaintiffs' untimely Opposition to Torrent's motion to clarify should be disregarded. In the September 18, 2024 Hearing, the Court properly ruled that it "can't have a plaintiff's expert opining as to a matter that the defendant's expert is not permitted to opine as to." Tr. 102:14-103:2.<sup>1</sup> Plaintiffs have no answer to this. Dr. Nagaich opines on the same topics as Mr. Russ. Indeed, most of his excluded opinions are *directly in response to and cite* opinions proffered by Mr. Russ. That the Liability Opinion would preclude Torrent and Dr. Nagaich from responding to Mr. Russ's opinions is manifestly unjust and would generate clear (and potentially reversible) error.

Confronted with that reality, Plaintiffs rely on four arguments designed to skirt the issue rather than address it. *First*, Plaintiffs argue that Torrent's motion was untimely. But Torrent timely filed its motion just nine days after the September 18 Hearing. Moreover, Plaintiffs' timeliness complaint rings hollow when their own Opposition was filed late. And, in any event, the Court should not risk reversible error based on technical timing arguments. Justice demands that Dr. Nagaich be permitted to testify in response to Mr. Russ regarding Dr. Yang's qualifications as an auditor, Dr. Yang's audit findings and their significance, and Torrent's compliance with industry standards. The Court should permit that testimony.

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<sup>1</sup> The terms defined in Torrent's Opening Brief are incorporated and used herein.

*Second*, Plaintiffs seek to recast the Court’s exclusion of Dr. Nagaich as one based on qualifications and reliability. But the Liability Opinion did not hold that Dr. Nagaich was unqualified as a cGMP expert. He is unquestionably qualified.

*Third*, Plaintiffs ignore that Dr. Nagaich’s opinions on compliance with industry standards were excluded because the Court held that they were legal opinions, but held that Mr. Russ’s opinions on non-compliance were permissible. That is the exact issue the Court addressed as to Dr. Afnan. Plaintiffs make no argument that the September 18 ruling was incorrect or does not apply equally here.

*Fourth*, Plaintiffs’ arguments regarding the reliability of Dr. Nagaich’s opinions as to Dr. Yang’s qualification and audits are wrong. Plaintiffs’ argument simply rehashes the Liability Opinion’s finding that Dr. Nagaich failed to offer adequate support for his opinions. But Plaintiffs do not engage with the *substance* of Dr. Nagaich’s report at all, let alone as compared to that of Mr. Russ. That is because Dr. Nagaich’s opinions are well-supported and rely on a far more robust record than does Mr. Russ. If Mr. Russ’s methodology was reliable, then Dr. Nagaich’s methodology is likewise reliable.

## ARGUMENT

### I. PLAINTIFFS’ FAILURE TO TIMELY OPPOSE TORRENT’S MOTION WAIVES THEIR OPPOSITION ARGUMENTS.

Torrent’s motion to clarify was filed on Friday, September 27, 2024 and noticed for a motion day 24 days later—October 21, 2024. *See* [ECF No. 2866](#).

Plaintiffs' Opposition was required to be filed "at least 14 days prior to the original motion day." Local Civil Rule 7.1(d)(2). That meant Plaintiffs' Opposition was due no later than October 7, 2024. *Id.* However, Plaintiffs did not file their Opposition until October 8, 2024. *See ECF No. 2895.* As a result, the Court can reject Plaintiffs' untimely arguments and deem their Opposition waived. *See* Local Civil Rule 7.1(d)(7).

In light of their own untimeliness, Plaintiffs' focus on Torrent's purported untimeliness is disingenuous. *See Opp'n at 1, 3-4.* In any event, Torrent's motion is not untimely. Torrent's motion is one for clarification based on the Court's ruling during the September 18 Hearing. *See Br. at 1-2.* Torrent's motion was filed just nine days after the hearing, on September 27, 2024. *See ECF No. 2866.* To the extent Local Civil Rule 7.1(i) governs the timing of the motion, it was filed within 14 days of the September 27, 2024 hearing and is timely.

Plaintiffs cannot defeat Torrent's timely motion for clarification by recasting it as a motion for reconsideration. Plaintiffs' argument that Torrent's motion is untimely rests entirely on Torrent's citation to *Sheehan v. Delaware & Hudson Railway Co.*, 439 F. App'x 130, 133 (3d Cir. 2011). *See Opp'n at 3-4.* But that makes no sense. Torrent's citation to *Sheehan* was an *alternative* argument made to show the Court has the *discretion* to reconsider the Liability Opinion and to do so to

avoid unjust results. Br. at 8; *see also* Br. at 2, n.1. The Court’s discretion is not dependent on procedural technicalities.

In any event, the Court should exercise its discretion to address the risk of clear and reversible error in the Liability Opinion regardless of either parties’ timeliness arguments. Plaintiffs’ argument essentially invites the Court to risk reversible error by precluding Torrent’s expert from testifying on certain topics but allowing Plaintiffs’ expert to testify on the exact same topics. *See* Br. at 5-6 (citing *United States v. Lankford*, 955 F.2d 1545, 1552-53 (11th Cir. 1992)).

## **II. DR NAGAICH’S OPINIONS WERE NOT EXCLUDED BASED ON HIS QUALIFICATIONS.**

Plaintiffs argue that “Dr. Nagaich’s opinions” were excluded “because Dr. Nagaich lacked qualifications.” Opp’n at 5. But the Liability Opinion plainly states—in the very pages Plaintiffs cite to support this mistaken claim—that “[t]he Court does not disqualify Nagaich.” Liability Op. at 14.

It is true that the Liability Opinion did (unfairly) “*question* [Dr. Nagaich’s] overall qualification to opine on the sufficiency of Torrent’s cGMP compliance.” Liability Op. at 14 (emphasis added). But the Court offered no explanation *why* it questioned Dr. Nagaich’s qualifications. The Court simply described Dr. Nagaich’s work over the past 10 years, without making any observations that Dr. Nagaich’s work in that time as “an independent Senior FDA / industry consultant, advising pharmaceutical companies on regulatory strategies and clinical development of

drugs, vaccines, biologics, etc.” would render him unqualified. *Id.* The Court found Mr. Russ’s similar—albeit longer—period of working as an industry consultant to sufficiently qualify him to testify on the same topics with respect to which Dr. Nagaich was excluded. *See Id.* at 25 (“Russ’s specific qualifications are his work as [a] consultant to pharmaceutical management for nearly 30 years in cGMP compliance.”).

Plaintiffs do not offer any actual argument that Dr. Nagaich is unqualified. In fact, Plaintiffs’ motion to exclude Dr. Nagaich made no argument that he was unqualified. *See generally ECF No. 2301-01.* Dr. Nagaich is eminently qualified on just the experience the Court highlighted from just the past 10 years, which includes hosting FDA inspections, conducting internal GMP audits, “conduct[ing] GMP compliance audits for . . . ingredient manufacturing facilities” on behalf of United States Pharmacopeia (“USP”), and conducting “technical due diligence audits, mock preapproval inspections, GxP audits, and vendor qualification audits” on behalf of pharmaceutical companies. *See* Nagaich Rpt. ¶¶ 6-10. And prior to that time, Dr. Nagaich spent eight years as a principal investigator and drug quality reviewer at the FDA, where he received extensive training in and experience conducting cGMP compliance inspections of drug and biologic manufacturing sites. *Id.* ¶¶ 3-4.

### **III. DR. NAGAICH'S OPINIONS REGARDING TORRENT'S COMPLIANCE WITH INDUSTRY STANDARDS CANNOT BE EXCLUDED AS LEGAL OPINIONS IF MR. RUSS IS PERMITTED TO TESTIFY ON THE SAME TOPIC.**

To the extent the Liability Opinion did exclude Dr. Nagaich based on his qualifications, it was based on the Court's determination that opinions that "Torrent followed industry standards" were "legal opinion[s] Nagaich is unqualified to make." Liability Op. at 15 (excluding paragraphs 79-80, 88-94, 95-97, and 104 for this reason or similar). That is the *exact same reasoning* that the Court rejected with respect to Dr. Afnan. *Compare id.*, with Liability Op. at 6-7 (precluding certain opinions of Dr. Afnan "because they cross over into legal opinions for which he is unqualified to assert").<sup>2</sup>

Plaintiffs make no argument that the Court's ruling as to Dr. Afnan should not apply to the relevant paragraphs of Dr. Nagaich's testimony. *See* Br. at 4-5, 7, 9-10.<sup>3</sup> Plaintiffs do not, because they cannot, explain why it would be improper for

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<sup>2</sup> Plaintiffs argue that "Dr. Afnan's opinions on adulteration were excluded for qualifications reasons." Opp'n at 5. In reality, Dr. Afnan opinions on adulteration were excluded based on the Court's determination that those opinions "cross over into legal opinions for which he is unqualified to assert." Liability Op. at 6. Nothing in the Liability Opinion questioned Dr. Afnan's qualifications as a cGMP or industry standards expert. *See id.* at 6-7.

<sup>3</sup> To the extent Plaintiffs argue that Dr. Nagaich's opinions on industry standards are *unreliable*, that argument fails for two reasons. *First*, the Liability Opinion made no such determination as to those opinions, which were excluded only on the basis that they were legal opinions. *See* Liability Op. at 15. *Second*, any

(cont'd)

Plaintiffs’ expert to opine that ZHP’s products were adulterated while preventing ZHP’s expert from saying the opposite, but not improper for Plaintiffs’ expert to opine that Torrent did not follow industry standards while preventing Torrent’s expert from saying the opposite. As the Court has already correctly held, it “can’t have a plaintiff’s expert opining as to a matter that the defendant’s expert is not permitted to opine as to.” Tr. 102:14-103:2.

**IV. DR. NAGAICH’S OPINIONS REGARDING DR. YANG’S QUALIFICATIONS AND AUDITS CANNOT BE EXCLUDED AS UNRELIABLE BECAUSE DR. NAGAICH USED THE SAME METHODOLOGY AS MR. RUSS.**

Plaintiffs’ argument that Dr. Nagaich’s opinion’s regarding Dr. Yang’s qualifications and audits contained in paragraphs 73-78 of his report were properly excluded on reliability grounds falls flat. Plaintiffs argue that Dr. Nagaich “never said why and he never explained *how* he reached [his] conclusion” that Dr. Yang

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argument that Dr. Nagaich failed to review certain “pertinent documentation,” Opp’n at 5 (emphasis omitted) goes to weight. *See, e.g.*, Tr. 111:1-12 (questioning Dr. Afnan about documents he had not reviewed went to weight, not reliability); *id.* 114:25-117:20 (same). The Court clearly explained this at the September 18 Hearing: “He relies upon a document in his expert report. That document says it was raining on the day in question. There are other documents out there that somehow show that it was sunny that day. He has rendered his report based on the fact that he believed it was raining. If the jury discredits that assumption by whatever means, so be it. The jury may discredit that assumption or they may credit his assumption, but that’s a jury call. And this is a weight cross-examination.” *Id.* 117:7-14.

was qualified. Opp'n at 6. But Plaintiffs offer no citation to Dr. Nagaich's actual report or deposition for this baseless claim.

In reality, Dr. Nagaich explained that "Dr. Yang has a Ph.D. in organic synthesis and . . . multiple years of teaching, consulting, and auditing experience on ICH guidelines and GMP regulations." Nagaich Rpt. ¶ 73. That assessment of Dr. Yang's qualifications—which was supported by Dr. Nagaich's review of Dr. Yang's CV, *id.* ¶ 73 & n.108—immediately preceded, and was clearly the support for, Dr. Nagaich's conclusion that "Dr. Yang was qualified to audit an API manufacturing site." *Id.* ¶ 73.

Dr. Nagaich also thoroughly explained why Mr. Russ's opinion that Dr. Yang was not qualified is wrong. *Id.* ¶¶ 74-75. Dr. Nagaich explained that the only support Mr. Russ identified was a December 17, 2016 EIR,<sup>4</sup> explained what the FDA stated in that EIR, and that "Mr. Russ has ignored Torrent's written response . . . explaining [Torrent's] procedure to qualify auditors." *Id.* Dr. Nagaich further explained that Torrent's response to the FDA showed that Dr. Yang was "qualified based on his/her credentials such as educational qualifications, a practical experience

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<sup>4</sup> Plaintiffs' assert that it is "simply false" that Mr. Russ "reviewed only a single document." Opp'n at 6, n.2. But Torrent did not say that Mr. Russ only *reviewed* a single document. Torrent explained—just as Dr. Nagaich does—that Mr. Russ only "cites a single document" to support his qualifications opinion. (Br. at 3 (citing Russ Rpt. ¶¶ 116-18 (citing TORRENT-MDL2875-00010961)).

in audits and assessment of Auditor’s capability through discussion telephonically,” and that the FDA subsequently reviewed that response and Dr. Yang’s requalification and found “[n]o discrepancies.” *Id.* ¶ 75. Dr. Nagaich’s opinion is well-supported and clearly explained.

Tellingly, Plaintiffs offer no argument that Dr. Nagaich’s opinions regarding the substance of Dr. Yang’s audits (made in response to Mr. Russ’s opinions on the same topic) were unreliable. *See Opp’n at 6.* Dr. Nagaich thoroughly explained how Mr. Russ’s opinion was based on “cit[ing] a single email communication from Dr. Yang to Torrent” following her 2015 audit of ZHP. Nagaich Rpt. ¶ 76. Dr. Nagaich then went on to describe that email and explain that Mr. Russ was wrong because the evidence showed that “Torrent did in fact follow up . . . regarding the outcome of the audit, as is standard with any vendor audit.” *Id.* ¶ 77. Indeed, as Dr. Nagaich noted, both the single email Mr. Russ relied upon and Dr. Jaiswal’s deposition testimony “confirm[] that the parties continued to follow up to address observations.” *Id.* Dr. Nagaich also explained why Dr. Yang’s email “did not implicate any serious quality concerns about the Valsartan API.” *Id.* ¶ 78. Nothing about those opinions is unreliable, particularly because they are offered in response to Mr. Russ’s opinions about the content of the same email.

## **CONCLUSION**

For the foregoing reasons as well as those set forth in its Opening Brief, Torrent respectfully requests that the Court clarify that Dr. Nagaich may testify as to all topics disclosed in his expert report and, to the extent necessary, amend or correct its ruling on the parties' liability experts to allow Dr. Nagaich to so testify.

Dated: October 15, 2024

Respectfully Submitted:

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**CERTIFICATE OF SERVICE**

I, Alexia R. Brancato, an attorney, hereby certify that on October 15, 2024, I caused a copy of the foregoing document to be served on all counsel of record via CM/ECF and caused the unredacted version filed under seal to be served on all counsel of record by email.

/s/ Alexia R. Brancato

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